FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP)

Hilton Washington, D.C./Silver Spring
Silver Spring, Maryland

August 5, 2009

TENTATIVE ROSTER

ADVISORY COMMITTEE for PHARMACEUTICAL SCIENCE AND CLINICAL PHARMACOLOGY MEMBERS (Voting)

Jessie L-S. Au, Pharm.D., Ph.D.
Distinguished University Professor
The Ohio State University
Columbus, OH

Merrill Goozner (Consumer Representative)
Silver Spring, MD

Marilyn E. Morris, Ph.D.
Professor, Department of Pharmaceutical Sciences
University at Buffalo, State University of New York, School of Pharmacy
Amherst, NY

Anne S. Robinson, Ph.D.
Professor**,** Department of Chemical Engineering
University of Delaware
Newark, DE

Elizabeth M. Topp, Ph.D.(Chair)
Head, Department of Industrial and Physical Pharmacy
Purdue University
West Lafayette, IN

ADVISORY COMMITTEE for PHARMACEUTICAL SCIENCE AND CLINICAL PHARMACOLOGY MEMBERS (Non-Voting)

Richard J. Stec, Jr., Ph.D. (Industry Representative)
Vice President, Global Regulatory Affairs
Perrigo
Allegan, MI

Patricia C. Tway, Ph.D. (Industry Representative)
President
CMC Technical Navigator
Phoenixville, PA

TEMPORARY MEMBERS (Voting)

Kenneth R. Morris, Ph.D. (participation by phone)
Professor of Pharmaceutics
College of Pharmacy
University of Hawaii at Hilo
Hilo, HI

Harriet B. Nembhard, Ph.D.
Associate Professor
Pennsylvania State University
University Park, PA

GUEST SPEAKERS (Non-Voting)

Challenges in the Development of Transdermal Drug Delivery Systems (TDDS)

Bozena B. Michniak-Kohn, Ph.D., M.R.Pharm.S.
Department of Pharmaceutics
Ernest Mario School of Pharmacy
Rutgers, The State University of New Jersey
Piscataway, NJ

Ravi Harapanhalli
Principal Consultant and Late Stage Services Lead
PAREXEL Consulting
Bethesda, MD

Classifying Pre-Surgical Preparations as Sterile Products

Michael Jhung, M.D., MPH
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Atlanta, GA

Status and Implementation of ICH Q8, Q9, and Q10 Quality Guidelines

Robert G. Baum, Ph.D.
Executive Director
Global CMC Regulatory Policy
Pfizer Global Research & Development
Groton, CT

Jean M. Wyvratt, Ph.D.
Vice President,
Analytical Chemistry in Development
and Supply, Global Science, Technology
and Commercialization
Merck Manufacturing Division
Rahway, NJ

Swroop Sahota, Ph.D., MBA
Vice President, Global Quality Services
Global Quality Operations
Schering-Plough Corporation
Summit, NJ

FDA PARTICIPANTS (Non-Voting)

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Deputy Director, OPS, CDER, FDA

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Lawrence X. Yu, Ph.D. (Topic 1)
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